In re Application of: Shih *et al*
Serial No.: 09/431,519
Filed: November 1, 1999

REMARKS

A Notice of Appeal for this application was filed June 7, 2005. The time for filing an Appeal Brief or response to the Notice of Appeal will expire on August 7, 2005. Applicants are filing this response on or before August 7, 2005. Accordingly, it is respectfully submitted that this response is timely filed. If any additional fee is due, the Commissioner is hereby authorized to charge the same to Deposit Account No. 19-0365.

Claims 1-20 are pending in the application. Claims 1-20 stand rejected. Claims 21-42 were withdrawn by the Examiner. In their Response to the Final Office Action dated May 9, 2005, Applicants canceled claims 1-20 and added new claims 43-57. However, the May 9, 2005 Amendments and Response were not entered because, "The proposed amendment is in comprising guise, while applicant argues the prior art is excluded because the instant invention is limited only to zeranol; it's not." See Examiner's May 24, 2005 Advisory Action. In response to the Examiner, applicants are filing the present amendment to address those concerns.

With this response, applicants have canceled claims 1-20 and applicants have added new claims 43-57. Support for new claims 43-57 can be found in originally filed claims 1-20. No new matter has been added with the filing of this amendment. Applicants respectfully submit that since the claims 43-57 were not entered by the Examiner in the applicants' previous response, new claims 43-57 being herein submitted to satisfy the Examiner's concerns expressed in his Advisory Action.

In view of the new claims and remarks below, applicants respectfully submit that the application is in condition for allowance. Accordingly, applicants request reconsideration of the application, withdrawal of the rejections of record, and issuance of Notice of Allowance.

Supplemental Information Disclosure Statement

Applicants wish to thank the Examiner for the entry of the reference submitted by the applicants filed via the IDS with the May 9, 2005 Response to Final Office Action.

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Rejections under 35 U.S.C. §112 Second paragraph.

The Examiner rejected Claims 1-8 and 13-20 under 35 U.S.C. §112, second paragraph as being indefinite. Applicants respectfully traverse this rejection.

The Examiner stated that the claims are indefinite for reciting "derivatives" because said term is open to wide interpretation. The Examiner also stated that Somatotrophin is presumably misspelled, otherwise the Examiner is unfamiliar with this drug.

In response to the rejection, applicants have cancelled claims 1-20 and added new claims 43-57, thus traversing this rejection. The terms Somatotrophin and derivatives are not in the new claims. Therefore, applicants respectfully request the withdrawal of these rejections under §112, second paragraph.

Rejections under 35 U.S.C. §102 (b) and 35 U.S.C. §103.

The Examiner rejected Claims 1, 5 and 7-9, 13-15 and 20 under 35 U.S.C. §102 (b) as being anticipated by, or in the alternative, under 35 U.S.C. §103 as being obvious under Ivy (U.S. 4670949). Applicants respectfully traverse this rejection.

As an initial matter, in response to the Examiner's Advisory Action, applicants have submitted new claim 43 wherein the comprising language has been now amended to replace the objected to "comprising" language with the term "consisting of."

The Ivy formulation is a mixture of a growth-promoting hormone *and* zearalin. See Col. 1, lines 19-21. The Examiner conceded that the specific incorporation of applicants' claim 1 compounds were not shown by Ivy.

Applicants have cancelled claims 1-20 and added new claims 43-57 wherein the implant composition is now a composition comprising: (i) an immediate-release formulation comprising zeranol, and (ii) a controlled-release formulation comprising zeranol and a controlled-release agent, wherein said immediate-release formulation and said controlled-release formulation cooperate to effect said stimulation. Applicants respectfully suggest that claim 43 and dependent claims 44-57, comprising zeranol alone as the only anabolic agent are NOT obvious in light of Ivy's

formulation of a mixture of growth-promoting hormone and zearalin. Applicants' respectfully suggest that Ivy's use of a combination of growth hormones AND zearalin teaches away from the applicants' use of zeranol in the absence of growth promoting hormone. Accordingly, Applicants, therefore, respectfully request withdrawal of this rejection.

The Examiner rejected Claims 1, 5, 7-10 under 35 U.S.C. §102 (b) as being anticipated by, or in the alternative, under 35 U.S.C. §103 as being obvious under O'Callaghan. Applicants respectfully traverse this rejection.

The Examiner stated that in O'Callaghan, teaches sub Q implantable pellets, consisting of estradiol and progesterone, estradiol and trenbolone acetate (col. 2, p. 427). The Examiner stated that agents listed in O'Callaghan, although NOT specifically labeled as controlled or immediate release agents, could take on said characteristics.

A rejection under 35 U.S.C. §102 (b) requires that each and every element of a rejected claim be disclosed by the prior art relied upon by the Examiner for making this rejection. Applicants' new claims 43-57 are drawn to compositions comprising zeranol alone as the only anabolic agent. O'Callaghan is silent on the use of zeranol, thus rendering this 102(b) rejection moot. Accordingly, applicants respectfully request reconsideration and withdrawal of this rejection under 102(b).

Applicants respectfully suggest that new claims 43-57, are NOT obvious in light of O'Callaghan for the following reasons. Applicants respectfully suggest that there is no teaching O'Callaghan to suggest to or motivate one or ordinary skill in the art to practice the applicants' claimed invention in light of applicants new claims which are directed towards zeranol as the only anabolic agent. As stated above, O'Callaghan is silent on the use of zeranol; therefore, there is no teaching or suggestion that would render the claimed invention obvious to one of ordinary skill in the art. Therefore, applicants respectfully request the withdrawal of this rejection under §103.

The Examiner rejected Claims 1-20 under 35 U.S.C. §103(a) as being obvious under O'Callaghan, in view of Nessel (US 3920806), Stevens (US 5874098) and Dick (GB 2167662). Applicants respectfully traverse this rejection.

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The Examiner stated that O'Callaghan provides instant dual formulations, while being silent on excipients, diluents, bulking agents, etc. (see above). The Examiner stated that Nessel shows a conventional lactose vehicle (col. 2, lines 35-37), and provide for immediate release, while polymer forms provide controlled release, the polymer prolonging release to 8 weeks only.

The Examiner is of the belief that Stevens shows implantation of multiple pellets (fig. 1, 2) sub Q to cattle ear but also that immediate release and controlled release were known at the time of the invention. using different actives (formula I and II).

The Examiner stated that were one to wish to have a biodegradable, implant of O'Callaghan type, it would have been obvious and within the purview of one in the implantation arts to utilize the Stevens ingredients by adjusting the pellets in terms of ratios of quick to controlled release, when the same active is desired, or to choose an immediately releasable compound (i.e. Stevens or Trenbolone of O'Callaghan) with a controlled release formulation, such as the estradiol/progesterone examples in order to achieve the results of O'Callaghan but without the need of retained implant slaughter.

The Examiner stated that Nessel described the use of a formulation as conventional lactose vehicle (col. 2, lines 35-37), for pharmaceutical compositions. The Examiner stated that Nessel polymers released 100% by 8 weeks, the problem O'Callaghan attempts to solve, with extension to 52 weeks.

The Examiner stated that Dick et al. shows the residual problem was known and that prolonged delivery was not.

As stated above, there is no teaching in O'Callaghan to suggest or motivate one or ordinary skill in the art to practice the applicants' compositions comprising zeranol alone as the only anabolic agent. Further, none of the cited references, Nessel, Stevens or Dick, teach the claimed invention's combination of zeranol as an immediate release in combination zeranol as a controlled release composition. Nessel, Stevens and Dick all merely demonstrate the basic concepts of using pharmaceutical excipients as potential means of controlling the release of active drug compounds. As explained above, O'Callaghan remains silent on the use of zeranol. None of the additional references disclose or suggest any teaching or

motivation that can be combined with O'Callaghan, in order to render obvious the applicants' invention obvious. Applicants, therefore, respectfully request withdrawal of this rejection under 35 U.S.C. §103.

Applicants respectfully submit that in view of the above response, applicants have sufficiently addressed the Examiner's rejections and that the application, as amended, is in condition for allowance.

If any additional fees are determined to be due by this paper, the Commissioner is hereby authorized to deduct such fees from **Account No. 19-0365**.

If for any reason the Examiner believes that an interview would be helpful to resolve any remaining issues, he is invited to telephone the undersigned at the number listed below.

Respectfully submitted,

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